

REMARKS

Administrative Overview

Applicants amend the title as reflected in the Amendment to the Specification hereinabove. The amended title is reflective of the pending claims, and the amendment is supported in the specification as originally filed. No new matter is added hereby.

The Office action of December 19, 2005, examined claims 105-111, 113, 115-119, 121-126, 148, 150, 152-156, 159, 160, and 162-168. The Office action rejected each of these claims under 35 U.S.C. 103(a) as being unpatentable over one or more references in combination with U.S. Patent No. 5,024,529 (**Svetkoff**).

The Office action alleges, “**Svetkoff et al** is just one example of many which discloses the use of a field stop which comprises an electromechanical shutter (column 7, lines 50-68).”

Without acquiescing to any rejection, but in an effort to advance prosecution of the case to allowance, Applicants amend claim 105 to remove the “controlling a field stop” limitation and to add the limitation, “wherein a disposable device for use with a single patient is positioned to protect said patient during said scanning.” This amendment is supported in the application as originally filed, for example, at page 37, line 28, to page 38, line 22, as follows [emphasis added]:

In situations where body cavities are being accessed by endoscopes, or laparoscopes, it is important to provide a system and a method that is adapted for these medical uses. It is furthermore important to provide systems and methods adapted for other medical uses, where the hardware probe is being used for in vivo diagnosis of biological tissues. Since the hardware probe is able to be placed into contact with biological tissues, contamination of the optical hardware probe must be avoided. A disposable probe or a disposable covering for the optical hardware probe may be particularly advantageous in these circumstances. A disposable device can be designed for a particular anatomic application. Procedures involving the gastrointestinal tract, the urinary tract, the peritoneal cavity, the thorax, and the female reproductive tract are examples of where a disposable device may be used. It will be especially advantageous to provide the hardware of the present invention with a disposable cover or sheath that can be adapted for use on a single patient. The term sheath as used herein is understood to encompass any device that fits over part or all of the optical hardware probe and that is thereby interposed between the probe and the in vivo biological tissues of a patient.

FIG. 17 shows an anatomic partial cross-sectional view of the female perineum depicting an embodiment of a disposable sheath 400, here shown in cross-section, positioned within the vagina 408. Adjacent structures including the bladder 462, the uterus 460, the rectum 464 and the symphysis pubis 466 are shown here to facilitate orientation. This figure shows an embodiment in which a disposable sheath 400 can be provided for an optical hardware probe 402 to illuminate the cervix 404. Configurations for the sheath 400 can be adapted to the anatomy of the cervix 404 and vagina 408. The white light illumination 410 of the cervix 404 can be provided circumferentially. The distance from the distal end 412 of the probe 402 to the cervix 404 may be about 100 mm. The probing beam 414 of the optical hardware probe 402 can be transmitted through the disposable protective sheath 400 to strike the cervix 404.

No new matter is added thereby. Dependent claims 115, 121, 123, and 126 are amended in light of the amendment of independent claim 105, and new dependent claim 170 is added. New claim 170 is supported in the application as originally filed, for example, in the excerpt reprinted above – “a disposable probe” – no new matter is added.

Similarly, without acquiescing to any rejection, but in an effort to advance prosecution of the case to allowance, Applicants amend independent apparatus claim 152 to remove the “at least one field stop” limitation and to add, “a disposable device for use with a single patient, said disposable device configured to protect said patient during said scanning.” This amendment is supported in the application as originally filed, for example, at page 37, line 28, to page 38, line 22, reprinted above – no new matter is added.

Dependent claims 159, 162, 167, and 168 are amended in light of the amendment of independent claim 152, and new dependent claim 171 is added. New claim 171 is supported in the application as originally filed, for example, in the excerpt reprinted above – no new matter is added.

Following entry of this amendment, claims 105-111, 113, 115-119, 121-126, 148, 150, 152-156, 159, 160, 162-168, 170, and 171 will be pending.

Amended independent claims 105 and 152 are patentable over the cited art

Independent claims 105 and 152 are amended to recite “a disposable device”. Previously-examined dependent claims 115, 126, and 167 included a “sheath”, or “single-use disposable sheath” limitation. The Office action addresses these limitations in its rejection of these claims under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 6,424,852 (**Zavislán**) in view of **Svetkoff**, asserting the following:

Zavislán discloses an optical system for diagnosing tissue using a confocal illuminating and detecting arrangement. The sheath can comprise[] the elements shown in figures 9-11 which prevent the imager 83 from contacting the tissue. The sheath is capable of being used only a single time and can be disposed of.

Applicants respectfully traverse these rejections and assert that **Zavislán** does not disclose a “disposable device for use with a single patient ... [positioned/configured] to protect said patient during said scanning,” as recited in claims 105 and 152. There is no mention of a protective disposable device, such as a single-use sheath, in **Zavislán**. Even if **Zavislán** could be considered to teach a “sheath”, there is no suggestion in **Zavislán** that such a sheath be configured for a single use, or that such a sheath be disposable.

Figures 9-11 of **Zavislán** (the figures recited in the Office action) show a system for applying a vacuum to immobilize skin tissue for imaging. This is not a system for protecting a patient during scanning. The description of Figures 9-11 of **Zavislán** appears at col. 6, line 26 to col. 7, line 6, reproduced in part, as follows [emphasis added]:

A third embodiment of the present invention is shown in FIGS. 9-11. This embodiment is provided by a tissue stabilization system 68 which includes an attachment 69. The tissue is shown at 84 in FIGS. 10-11 as a layer of skin. Attachment 69 includes a flexible diaphragm member 70, a central circular window or plate member 72, and a semi-rigid ring 74. Diaphragm 70 is composed of deformable rubber selected to be less compliant than tissue 84. Diaphragm 70 radially extends from window 72 outward to semi-rigid ring 74. Ring 74 may be composed of hard rubber, while window 72 may be composed of a material having an optical index approximately matching tissue 84. Diaphragm 70 has between ring 74 and window 72 an annular protruding section 75 (protruding in the direction of the arrow of FIG. 10). Section 75 defines outer and inner annular cavities 76 and 78, respectively. Also, attachment 69 has a pair of vacuum lines 80 which each connects different ones of annular cavities 76 and 78 to a pneumatic pump which selectively creates suction between diaphragm 70 and the surface 84a of tissue 84. The size or diameter of system 68 and its attachment 69 may be appropriately dimensioned for the skin surface area to be confocally imaged through window 72.

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In operation, attachment 69 is first placed over surface 84a of tissue 84 such that diaphragm protruding section 75 is adjacent to surface 84a, as shown in FIG. 10. When window 72 is located over the area of tissue 84 to be confocally imaged, the air is evacuated via vacuum lines 80 from each cavity 76 and 78. This

creates suction which pulls tissue 84 up into cavities 76 and 78, as shown in FIG. 11. As a result, semi-rigid ring 74 and window 72 are pulled downward onto surface 84, and the tissue beneath window 72 is placed under stress, such as by tension or compression. In this mode, attachment 69 engages or adheres by suction to the surface 84a of the tissue.

Zavislán does not teach or suggest that the “attachment” is a disposable device, or that the “attachment” is configured to protect the patient during a scan. On the contrary, the “attachment” of **Zavislán** appears to include a rubber diaphragm used to maintain a vacuum and keep the skin still during imaging. As stated in the Abstract of **Zavislán** [emphasis added]:

The mechanism includes a mechanical structure, such as a platen, brace, or attachment, which both supports the imaging head of the system and applies stress to a limited surface area of the tissue to minimize skin motion during confocal imaging.

Such an attachment would not be disposable, nor would it be a single-use component. There is no suggestion in **Zavislán** to change the “platen, brace, or attachment” between scans.

The cited art does not teach the limitation, “wherein a disposable device for use with a single patient is positioned to protect said patient during said scanning.” Therefore, the cited art does not teach or suggest every element of claim 105, and claim 105 is patentable in light of the cited art. Applicants respectfully request that the rejection of claim 105 be reconsidered and withdrawn.

Similarly, the cited art does not teach the limitation, “a disposable device for use with a single patient, said disposable device configured to protect said patient during said scanning.” Therefore, the cited art does not teach or suggest every element of claim 152, and claim 152 is patentable in light of the cited art. Applicants respectfully request that the rejection of claim 152 be reconsidered and withdrawn.

Dependent claims 106-111, 113, 115-119, 121-126, 148, 150, 153-156, 159, 160, and 162-168 are patentable over the cited art

Since a dependent claim includes all the limitations of the independent claim from which it depends, Applicants respectfully request that the rejections of dependent claims 106-111, 113, 115-119, 121-126, 148, 150, 153-156, 159, 160, 162-168, 170, and 171 be reconsidered and withdrawn, at least for reasons described with respect to independent claims 105 and 152 as presented above.

Application No. 09/841,325
Response dated Monday, March 20, 2006
Reply to Final Office Action of December 19, 2005

Conclusion

In view of the foregoing, Applicants request reconsideration, withdrawal of all rejections, and allowance of claims 105-111, 113, 115-119, 121-126, 148, 150, 152-156, 159, 160, 162-168, 170, and 171 in due course.

If the Examiner believes that it would be helpful to discuss any aspect of the application by telephone, the undersigned representative cordially invites the Examiner to call at the telephone number given below.

Respectfully submitted,



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